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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	24001-010	7314

7590 11/15/2002

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,969	PITTNER ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *2,3,13-22,24-28 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,23,29 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 9 on October 7, 2002 has been entered in full. Claim 33 has been amended. Claims 1-33 are pending and claims 1, 4-12, 23, 29, and 31-33 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Objections and/or Rejections

The objection to Claim 23, as set forth at page 5 of the previous Office Action (Paper No. 7, August 16, 2002), has been withdrawn because it was caused by a typographic error.

III. Claim Rejections Under 35 U. S. C. § 103 (a)

The 103(a) rejection set forth at pages 3-5 of previous office action (Paper No. 7, August 16, 2002) has bee modified with the addition of reference by Ueno et al. and replaced by the following rejection.

Claims 1, 4, 4-12, 23, 29, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaisse-Lagae et al. (*IDS*, *Experientia* 33:915-917, 1977) in view of Yoshinaga et al. (*IDS*, *Am. J. Physiol.* 263:G695-701, 1992), Allen et al. (*IDS,*

Digestion 30:255-262, 1984), and Ueno et al. (IDS, Gastroenterology, 117:1427-1432, 1999).

Malaisse-Lagae et al. teach a method of treating obesity comprising administering to obese mice a therapeutive effective amount of pancreatic polypeptide (See, e.g., Abstract). Peripherally administration of 5 μg/kg body weight per dose or 50 μg/kg body weight per dose (two daily injections) reduced food intake and suppressed body weight (Page 916).

Malaisse-Lagae et al. fail to teach (i) the use of peptide YY (PYY) or PYY agonist, e.g., PYY[3-36]; (ii) the relative potency of a PYY agonist and NPY.

Yoshinaga et al. teach the structural requirements of peptide YY for inhibition of pancreatic exocrine, gastric acid, and insulin secretion (See, e.g., Abstract). Yoshinaga et al. also teach the effects of PYY and PYY-related peptides, including a PYY agonist, PYY[3-36], and [Leu31, Pro34]NPY on gastric acid output. Yoshinaga et al. show that PYY has a greater potency than [Leu31, Pro34]NPY in gastric emptying assay (e.g., Fig. 2 and Table 3).

Allen et al. teach that infusion of PYY resulted in a significant delay in gastric emptying of glucose, whereas infusion of NPY at the same rate had no significant effect on the rate of gastric emptying (See, e.g., Abstract). Combining the teaching of Yoshinaga et al. with the teaching of Allen et al., it is reasonably assumed that PYY[3-36] has a greater potency than NPY in gastric emptying assay.

Ueno et al. (IDS, Gastroenterology, 117:1427-1432, 1999) teach decreased food intake and body weight in pancreatic polypeptide-overexpressing mice and that

physiological doses of PP inhibit pancreatic exocrine secretion (1st paragraph of right column of page 1427).

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the PYY and a PYY agonist, e.g., PYY[3-36], in the method of treating obesity as taught by Malaisse-Lagae et al. with a reasonable expectation of success. One would have been motivated to do so because both PP and PYY belong to the pancreatic polypeptide family and both function as inhibitors of pancreatic exocrine as taught by Yoshinaga et al. (See, e.g., Abstract) and by Ueno et al. (bottom of left column to top of right column of page 1427).

Applicants argue (i) that it is not relevant whether Malaisse-lagae shows decreased food intake and reduced weight gain in ob/ob mice because PP is not the same peptide as a PYY or PYY agonist of the invention; and (ii) that PP, PYY, and NPY are all members of the pancreatic polypeptide family, they behave quite differently with respect to gastric emptying actions, so one of skilled in the art would not be motivated and would not have a reasonable expectation of success in substituting these peptides for any given purpose. This has been fully considered but is not deemed to be persuasive for the following reasons.

First, Malaisse-Lagae et al. teach a general method of treating obesity comprising administering to obese mice a therapeutive effective amount of pancreatic polypeptide (PP). For a claim rejection under 35 U.S.C. 103 (a), the peptide used in the method does not need to be the same peptide as disclosed in the present invention.

Second, Yoshinaga et al. and Allen et al. teach that PYY and PYY-related peptides, including a PYY agonist, PYY[3-36], and [Leu31, Pro34]NPY function as potent inhibitors of pancreatic exocrine, gastric acid, insulin secretion.

Third, Ueno et al. (IDS, Gastroenterology, 117:1427-1432, 1999) teach decreased food intake and body weight in pancreatic polypeptide-overexpressing mice and that physiological doses of PP inhibit pancreatic exocrine secretion (1st paragraph of right column of page 1427).

Therefore, one skilled in the art would be motivated at the time the invention was made to substitute PP with the PYY or a PYY agonist (e.g., PYY[3-36]) as taught by Yoshinaga et al. in the method of treating obesity as taught by Malaisse-Lagae et al. with a reasonable expectation of success because both PP and PYY are members of pancreatic polypeptide family and both inhibit pancreatic exocrine secretion.

VI. Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

Ruixiang Li
Examiner
November 12, 2002